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ART UNIT	PAPER NUMBER
4114	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/824,130	FORTH ET AL.	
	Examiner	Art Unit	
	JOSEPH BURGESS	4114	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/26/2004,11/24/2004,01/09/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to application 10/824130 filed on 04/13/2004.

2. Claims 1-32 are currently pending and have been examined.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

5. The independent claims recite several steps: "activating" and "determining," but the claims and specification do not provide any particular structure or method by which to perform these steps.

6. The claims describe the desired result of a function, for example: "….activate said authentication codes for pharmaceutical packages that are being sent to destination sites…" in claim 1. The claim itself does not define the structure or method of the function used to reach that result. The claimed limitation does not fall under 35 USC § 112 ¶ 6 - "means for," which would allow the scope of the claim to be defined as the particular methods or structure enumerated in the specification. Further, one of ordinary skill in the art would not understand these limitations to imply any particular structure or method. Therefore, the claim is properly construed to

encompass any and all means for, for example, "….activate said authentication codes for pharmaceutical packages that are being sent to destination sites…"

7. When a limitation encompasses any and all structures or acts for performing the recited function, including those which were not what the applicant had invented, the disclosure fails to provide a scope of enablement commensurate with the scope of the claim. See Ex parte Miyazaki, Appeal No. 2007-3300, p. 27 (BPAI, 2008) (referencing Halliburton Oil Well Cementing Co. v. Walker, 329 US 1 (1946)). Because the disclosure does not enable every structure and act that reasonably falls within the claim's scope, the disclosure fails to provide an adequate scope of enablement as required by 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 101

8. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

9. Claims 11-16 and 24-32 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 11-16 and 24-32 are directed to a method. However, the recited steps of the method are held to be non-statutory subject matter because they are (1) not tied to another statutory class (such as a particular apparatus) or (2) not transforming the underlying subject matter (such as an article or materials) to a different state or thing.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Examiner's Note: The Examiner has pointed out particular references contained in the prior art of record within the body of this action for the convenience of the Applicant. Although the specified citations are representative of the teachings in the art and are applied to the specific limitations within the individual claim, other passages and figures may apply. Applicant, in preparing the response, should consider fully the entire reference as potentially teaching all or part of the claimed invention, as well as the context of the passage as taught by the prior art or disclosed by the Examiner.

12. Claims 1-17, 21, and 23-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael, et al. (US 2003/0088442 A1) in view of Cunningham (US 6,859,780 B1) in further view of Moore (US 6,456,729 B1).

13. **Claim 1:**

Michael, as shown, discloses the following limitation:

- *an activation computer configured to store authentication codes in a database and associate said authentication codes with pharmaceutical packages* (see at least paragraphs 0022-0023

and 0076, i.e. automatic identification codes or barcodes are associated with drug samples and are stored in a main inventory database),

Michael does not disclose the following limitation, but Cunningham as shown does:

- *wherein said activation computer is further configured to activate said authentication codes for pharmaceutical packages that are being sent to destination sites* (see at least column 3, lines 10-34, i.e. pharmaceutical trial media is activated by the central computing station to validate that prescription will be available at pharmacy destination);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *an authentication computer configured to receive authentication codes that are read from pharmaceutical packages received at said destination sites and determine whether said authentication codes have been activated* (see at least column 6, lines 8-36, i.e. a field reader identifies the codes on marked packages that have been shipped to a field destination and then validates the codes).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the code validation technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the

authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

14. Claim 2:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said activation computer is configured to store additional information for said pharmaceutical packages in said database along with said activated authentication code* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

15. Claim 3:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the authentication computer is configured to determine whether information received in connection with an authentication code corresponds to the additional information stored at said database* (see at least paragraphs 0076-0080, i.e. barcodes that include additional information about a drug sample are read by scanner at destination and this information is validated by main inventory database during synchronization process).

16. Claim 4:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional information includes at least one of: pharmaceutical package destination information, pharmaceutical type, pharmaceutical quantity, pharmaceutical dosage, or pharmaceutical manufacturer information* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to

each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

17. Claim 5:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the authentication code is a machine readable code* (see at least paragraph 0078, i.e. barcode can be read by barcode reader).

18. Claim 6:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *said authentication computer is configured to receive authentication codes from a code reader* (see at least column 6, lines 8-36, i.e. host computer receives data from field reader). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the code reader of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

19. Claim 7:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *a server in communication*

with said database, said activation computer, and said authentication computer, wherein said server transmits an activated authentication code to said authentication computer, and said authentication computer is configured to store the activated authentication code received from said server (see at least column 10, lines 27-49, i.e. prescriber terminal communicates identification codes to central computing station which stores these in its database). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code storage function of Cunningham because it allows for codes to be readily available to be verified when they are sent from the readers to the authentication computer which allows for more efficiency in tracking pharmaceutical products.

20. Claim 8:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said additional information comprises the intended destination of said pharmaceutical packages* (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication computer to determine if the product has reached its intended destination which makes the shipping process more secure.

21. Claim 9:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *the intended destination includes intermediate and final destination information* (see at least paragraph 0023, i.e. manufacturer ships drug samples to pharmaceutical representative who ships them to doctors and this is all tracked thru the automatic identification code that is marked on the samples).

22. Claim 10:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said authentication computer is configured to notify said activation computer in response to determining that a received authentication code corresponding to a pharmaceutical package is not an activated authentication code* (see at least column 10, lines 13-26, i.e. prescriber terminal determines that the product media is not valid and is therefore not activated). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the non-activated code determination of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall pharmaceutical shipping environment.

23. Claim 11:

Michael, as shown, discloses the following limitations:

- *storing said authentication code and additional product distribution information to a database* (see at least paragraph 0078, i.e. pharmaceutical sample barcode is read by reader and product information as well as information relating to the same is logged into local database)*;*
- *reading the unique authentication code at said destination site* (see at least paragraph 0078, i.e. barcode on sample is read by reader when shipped to pharmaceutical representative)*;*
- *verifying the read authentication code and additional product distribution information with said database* (see at least paragraphs 0076-0080, i.e. read barcodes and additional information are synchronized back to main inventory database to verify information)*;*

Michael does not disclose the following limitations, but Cunningham as shown does:

- *activating said unique authentication code to indicate that said pharmaceutical package is being sent to a destination site* (see at least column 3, lines 10-34, i.e. pharmaceutical trial

media is activated by the central computing station to validate that prescription will be available at pharmacy destination);

- *notifying said system server whether said verification was successful* (see at least column 10, lines 13-26, i.e. if product trial media is deemed authentic, then prescriber terminal displays that the product trial media is valid);
- *expiring said activated authentication code in response to a successful verification of said authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the unique code system of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *correlating a unique authentication code with a pharmaceutical product package and additional product distribution information* (see at least column 1, lines 16-31, i.e. packaged goods are issued a unique mark to help determine such information as the final point of destination and other information);

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the unique authentication code of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine

such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

24. Claim 12:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional product distribution information includes at least one of destination information for a pharmaceutical product, manufacturer information for said product, receiving location information, product type, or product quantity* (see at least paragraph 0078, i.e. barcodes issued from manufacturer's location and attached to each drug sample provide information relating to that sample such as product type, lot number, expiration date, etc).

25. Claim 13:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional product distribution information is stored in a computer at said destination site* (see at least paragraph 0078, i.e. barcodes that include additional information about a drug sample are read by scanner at destination and this information is stored logged into a local database).

26. Claim 14:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said additional information is input by a user* (see at least paragraphs 0078-0079, i.e. product's additional information can be manually input).

27. Claim 15:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *sending an authentication request, said authentication code read from said product packaging and said additional product distribution information to a system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database),

Michael does not disclose the following limitation, but Cunningham as shown does:

- *determining, in response to said authentication request, whether said authentication code read from said product packaging was an activated authentication code, and notifying said system server of the result of said determination* (see at least column 10, lines 13-49, i.e. central computing station determines if product media is activated and notifies associated database that it is activated).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the activated code determination of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

28. Claim 16:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *verifying the read authentication code and additional product distribution information with said database comprises sending encoded data to said database* (see at least column 7, lines 14-41, i.e. encoded data including the final point of distribution and unique manufacturer identifier are applied to packages, scanned,

and compared to stored encoded input data entries in the mass storage device data). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the ability to send encoded product data a database of Moore because it, "...provides a method for controlling and enabling the authentication and tracking of consumer goods to reduce the amount of counterfeit goods and to reduce the shipping of authentic goods to unauthorized points of final distribution..." (Moore, column 7, lines 14-18).

29. Claim 17:

Michael, as shown, discloses the following limitation:

- *a first code reader configured to read authentication codes from product packaging* (see at least paragraph 0078, i.e. barcode reader scans barcode of pharmaceutical sample)*;*

Michael does not disclose the following limitation, but Cunningham as shown does:

- *an activation module configured to receive an authentication code read by said first code reader from product packaging prior to distribution* (see at least column 10, lines 3-26, i.e. prescriber terminal receives product media coding from magnetic cards swiped into card reader)*, and to transmit an activation request to the system server* (see at least column 10, lines 27-49, i.e. prescriber terminal transmits activation requests to central computing station)*, wherein said activation request comprises the authentication code read by said first code reader* (see at least column 10, lines 27-49, i.e. product media information previously read into prescriber terminal is uploaded to central computing station)*, wherein the system server stores the authentication code as an active authentication code in response to the activation request* (see at least column 10, lines 27-49, i.e. central computing station stores product media information in database after activation).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate

reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *a system server including a first authentication module* (see at least column 6, lines 21-36, i.e. host computer uses database to validate code)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the system server of Moore because it allows for codes to be stored and authenticated by the manufacturer which provides for a more secure environment for the pharmaceutical supply chain.

30. Claim 21:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael discloses the limitation of *said destination information includes intermediate destination information and final destination information* (see at least paragraph 0023, i.e. manufacturer ships drug samples to pharmaceutical representative who ships them to doctors and this is all tracked thru the automatic identification code that is marked on the samples).

31. Claim 23:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *said activation module is further configured to encode said activation request, and to transmit said encoded activation module to said system server, and wherein said system server is configured to decode said encoded activation request* (see at least column 7, lines 14-41, i.e. packages are marked with unique activated code comprising encoded data which is also stored in a mass storage device, the code

is then scanned which decodes the pattern and allows the system to compare the encoded data against stored encoded data entries in the mass storage device). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the encoding and decoding technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

32. Claim 24:

Michael, as shown, discloses the following limitation:

- *applying an authentication code to product packaging* (see at least paragraph 0023, i.e. sample is marked with automatic identification code)*;*

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending an activation request to a system server, wherein said activation request includes the read authentication code* (see at least column 10, lines 3-49, i.e. code is read from magnetic cards and this code is downloaded from prescriber terminal to central computing station to validate activation)*;*
- *activating the read authentication code in response to the activation request, comprising storing the read authentication code as an active authentication code at the system server* (see at least column 10, lines 27-49, i.e. central computing station approves activation and stores code from activated product media in database).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the technique of sending and

storing activation codes of Cunningham because it makes sure the activation codes are available and secure when they are needed to verify packages are being shipped to their correct destinations.

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *reading the authentication code from the product packaging at the origin location prior to distribution* (see at least column 5, line 57 – column 6, line 6, i.e. at the place of origin for the packaging markings, a CCD camera validates that marks are appropriately printed on products)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the technique of reading the authentication code at the origin location of Moore because it allows for codes to be read and stored in computer memory as they are marked on packaging at the origin location. This makes the shipping process more secure in that it allows for validation of the package location from origination to final location.

33. Claim 25:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *reading an authentication code from product packaging received at a receiving location* (see at least paragraph 0023, i.e. automatic identification code from sample is read by scanning device when received from pharmaceutical company)*;*

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending the active authentication code to a product receiving location* (see at least column 10, lines 27-49, i.e. central computing station approves activation and sends specific approval code to prescriber terminal)*;*

- *determining whether said authentication code read at said receiving location corresponds to said active authentication code* (see at least column 10, lines 27-49, i.e. central computing station determines if code downloaded from prescriber terminal is activated)*;*
- *notifying a user of the result of said determination* (see at least column 10, lines 27-49, i.e. central computing station notifies prescriber terminal that activation is approved).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

34. Claim 26:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Michael, as shown, discloses the following limitation:

- *sending a verification request and said authentication code read at said receiving location to said system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database)*,*

Michael does not disclose the following limitations, but Cunningham as shown does:

- *determining whether said authentication code read at said receiving location corresponds to an active authentication code stored at said system server* (see at least column 10, lines 13-49, i.e. central computing station determines if product media is activated and notifies associated database that it is activated)*,*
- *notifying the receiving location as to whether the authentication code read from product packaging at the receiving location corresponds to an active authentication code stored at the system server* (see at least column 10, lines 27-49, i.e. central computing station notifies prescriber terminal that activation is approved).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the activated code determination and notification technique of Cunningham because it gives the authentication computer the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

35. Claim 27:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *expiring the active authentication code in response to determining that the authentication code read at the receiving location corresponds to the active authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product)*, wherein expiring comprises storing the active authentication code at the system server as an expired authentication code* (see at least column 11, line 61 – column 12, line 9, i.e. the central computing station stores a full record of all transactions including activations, validations and when pharmaceuticals have been expired and need to be replenished). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code expiring technique of Cunningham because it makes sure that the unique codes assigned to specific packages cannot be duplicated in the supply chain thus creating a more secure overall supply chain.

36. Claim 28:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham discloses the limitation of *said activation request*

includes destination information for the product (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier), *and wherein activating further comprises storing said destination information in connection with said active authentication code* (see at least column 10, lines 27-49, i.e. once product media is activated the central computing station stores the identity of the prescriber in the database). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication computer to determine if the product has reached its intended destination which makes the shipping process more secure.

37. Claim 29:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham, as shown, discloses the following limitation:

- *said activation request includes destination information for the product* (see at least column 6, lines 16-25, i.e. encoded information includes a pharmacy location identifier), *wherein activating further comprises storing said destination information in connection with said active authentication code at said system server* (see at least column 10, lines 27-49, i.e. once product media is activated the central computing station stores the identity of the prescriber in the database),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the identification of the intended destination technique of Cunningham because it allows the authentication computer to determine if the product has reached its intended destination which makes the shipping process more secure.

The combination of Michael/Cunningham does not disclose the following limitations, but Moore as shown does:

- *sending said destination information to a receiving location* (see at least column 11, lines 43-56, i.e. host computer sends message to field reader which displays pertinent information including destination),
- *determining whether receiving location information corresponds to said destination information from said system server* (see at least column 7, lines 34-41, i.e. encoded data is compared against data in mass storage device to determine if specified destination is correct),
- *notifying the receiving location as to whether the receiving location information corresponds to said destination information* (see at least column 11, lines 43-56, i.e. host computer sends message to field reader which displays pertinent information including destination and signals if package is counterfeit or has been received at wrong point of final distribution).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the destination determination and notification technique of Moore because it affords the system the opportunity to determine if drugs have been shipped inadvertently, to the wrong destination, or that there are counterfeit products in the supply chain thus creating a more secure overall supply chain.

38. Claim 30:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Moore discloses the limitation of *encoding said activation request, sending said encoded activation request to said system server, and decoding said encoded activation request at said server prior to said activating* (see at least column 7, lines 14-41, i.e. packages are marked with unique activated code comprising encoded data which is also stored in a mass storage device, the code is then scanned which decodes the pattern and allows the system to compare the encoded data against stored encoded data entries in the mass storage device). It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the

encoding and decoding technique of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

39. Claim 31:

Michael, as shown, discloses the following limitation:

- *reading an authentication code from product packaging received at a receiving location* (see at least paragraph 0078, i.e. barcode on sample is read by reader when shipped to pharmaceutical representative)*;*
- *sending a verification request and said authentication code read at said receiving location to said system server* (see at least paragraphs 0022-0023 and 0076-0080, i.e. barcode, including additional product information is scanned and stored in local destination database and then this information is sent to main inventory database for verification)*;*

Michael does not disclose the following limitations, but Cunningham as shown does:

- *sending an activation request, said read authentication code, and product destination information to a system server* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. destination and other encoded information is sent to central computing station to request activation of product media)*;*
- *activating said read authentication code in response to said activation request, comprising storing said read authentication code as an active authentication code and said product destination information at said system server* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. product media including destination and other encoded information is activated by central computing station which stores this information in associated database)*;*

- *verifying said authentication request, comprising comparing said authentication code read from product packaging at said receiving location to active authentication codes stored at the system server* (see at least column 10, lines 3-49, i.e. product media coding is read, validated by the prescriber terminal, the coding is uploaded to central computing station and activated once coding is compared to data in database)*;*
- *notifying said receiving location whether said authentication request was verified, comprising indicating whether said authentication code read from product packaging at said receiving location corresponds to said active authentication code* (see at least column 10, lines 3-49, i.e. central computing station notifies prescriber of activation once data is compared in database)*;*
- *expiring said active authentication code by storing said active authentication code at said system server as an expired authentication code* (see at least column 3, line 54 – column 4, line 3, i.e. product media are given a number of validations which expire once the validations are exhausted or the product media are unique for each pharmaceutical used and would expire with the prescription of each unique product).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the code activation technique of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitation, but Moore as shown does:

- *reading an authentication code from a product packaging at said origin location prior to distribution* (see at least column 5, line 57 – column 6, line 6, i.e. at the place of origin for the packaging markings, a CCD camera validates that marks are appropriately printed on products)*;*

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the technique of reading the authentication code at the origin location of Moore because it allows for codes to be read and stored in computer memory as they are marked on packaging at the origin location. This makes the shipping process more secure in that it allows for validation of the package location from origination to final location.

40. Claim 32:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. Furthermore, Cunningham, as shown, discloses the following limitation:

- *said activation request further comprises destination information* (see at least column 6, lines 16-25 and 10, lines 27-49, i.e. product media including destination and other encoded information is scanned at prescriber terminal which sends activation request to central computing station),

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael with the destination information of Cunningham because it allows, "...prescription drugs to be tracked such that appropriate reporting may be performed about the dispensation of prescription drugs..." (Cunningham, column 2, lines 57-59).

The combination of Michael/Cunningham does not disclose the following limitations, but Moore as shown does:

- *said method further comprises storing said destination information at said system server* (see at least column 8, lines 23-44, i.e. system allows for entering and storing a unique destination identifier into a CPU),
- *said verification request further comprises receiving location information* (see at least column 11, lines 43-56, i.e. host computer receives location information from field reader),

- *said verifying said authentication request further comprises comparing said receiving location information to said destination information* (see at least column 7, lines 14-41, i.e. method compares encoded data read from scanning to encoded data stored to mass storage device to determine if goods are authentic and if specified destination is correct),
- *said notifying said receiving location further comprises indicating whether said receiving location information corresponds to said destination information stored at said server* (see at least column 7, lines 14-41, i.e. method compares encoded data read from scanning to encoded data stored to mass storage device to determine if goods are authentic and if specified destination is correct).

It would have been obvious to one of ordinary skill in the art at the time of the invention to combine the drug inventory management system of Michael/Cunningham with the unique authentication code of Moore because it allows for, "...a system for controlling and enabling the marking and controlling the marking of goods, such as basic materials or articles of manufacture or packaged goods, with a unique mark, symbol, or pattern for subsequent detection to determine such information as the final point of distribution of authentic goods, the amount of unmarked goods in the market, i.e., counterfeit goods, the source of entry of the unmarked goods, the authenticity of the goods, the product distribution channels for the goods, the durability and/or lifetime of the goods, and other information..." (Moore, column 1, lines 18-28).

41. Claims 18-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Michael, et al. (US 2003/0088442 A1) in view of Cunningham (US 6,859,780 B1) in further view of Moore (US 6,456,729 B1) in further view of Official Notice.

42. **Claim 18:**

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *at least a second code reader configured to read authentication codes from product packaging, and*

a second authentication module, configured to receive an authentication code read by said second code reader from product packaging and active authentication codes from said system server, and configured to determine whether said authentication code read by said second code reader corresponds to said active authentication code received from said system server, and to notify a user of said second code reader as to whether the authentication code read by said second code reader corresponds to said active authentication code. However, the examiner takes Official Notice that is old and well known in the art to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

43. Claim 19:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *said second authentication module is further configured to transmit a verification request and said authentication code read by said second code reader to said system server, wherein said first authentication module is further configured to determine whether said authentication code received with said authentication request corresponds to an active authentication code stored at said system server, and wherein the first authentication module is configured to notify said*

second authentication module as to whether said authentication code received with said verification request corresponds to an active authentication code. However, the examiner takes Official Notice that is old and well known in the art to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

44. Claim 20:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *said activation request includes destination information for the product, said destination information is stored at the system server in connection with the active authentication code, said second authentication module is configured to receive said destination information from said system server with said active authentication code, and said second authentication module is further configured to determine whether information at said second code reader corresponds to said destination information received from said system server*. However, the examiner takes Official Notice that is old and well known in the art to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than

one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

45. Claim 22:

The combination of Michael/Cunningham/Moore discloses the limitations as shown in the rejections above. The combination of Michael/Cunningham/Moore fails to explicitly disclose *said first authentication module is configured to store said previously active authentication code as an expired authentication code when said second authentication module determines that said authentication module read by said second code reader corresponds to said active authentication module*. However, the examiner takes Official Notice that is old and well known in the art to have at least a second pharmaceutical tracking system in place when you already have a first one. For instance, in at least column 5, lines 41-56, Moore discloses that a system could comprise more than one computer or server, more than one marking system, more than one scanner or reader. Therefore, it would have been obvious to one of ordinary skill in the art to combine the drug inventory management system of Michael/Cunningham/Moore with the ability to have at least a second such system in place. The reason to combine a second drug inventory management system with the first would be because the manufacturer is shipping pharmaceuticals to multiple locations. Additionally, some of those multiple locations are just intermediate shipping points for the pharmaceutical products on their way to final destinations. This combination provides a

predictable result because it is well known to have multiple tracking systems for authenticating multiple packages shipped to multiple destinations.

Conclusion

This prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- Storch, et al. (US 5,548,110 A)
- Colella, et al. (US 6,003,006 A)
- Brook, et al. (US 6,170, 746 B1)
- Browne (US 2003/0216974 A1)
- "Using Covert Codes to Mark Healthcare Packages", Pharmaceutical and Medical Packaging News, Daphne Allen, page 24, October 1999
- "Raising the Bar: The Future of Bar Codes", Pharmaceutical and Medical Packaging News, Ralph Dillon, et al., page 59, March 2001

Any inquiry of a general nature or relating to the status of this application or concerning this communication or earlier communications from the Examiner should be directed to **JOSEPH BURGESS** whose telephone number is **(571)270-5547.** The Examiner can normally be reached on Monday-Friday, 9:30am-5:00pm. If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, **JAMES REAGAN** can be reached at (**571)272-6710**.

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02/20/2009

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